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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,262	02/01/2001	James L. McMenimen	P-9153.02	7232

27581 7590 08/13/2003

MEDTRONIC, INC.
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EXAMINER

JASMIN, LYNDIA C

ART UNIT

PAPER NUMBER

3627

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,262

Applicant(s)

MCMENIMEN ET AL.

Examiner

Lynda Jasmin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Amendment received on June 24, 2003 has been acknowledged.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-3 and 5-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-8 of copending Application No. 09/775,281 in view of Bradbury et al. (2002/0007294 A1).

Copending application 09/775,281 discloses all the limitation of claims 1-3 and 5-7, except for the teaching of the implanted medical device having specific features including customized featured having customized data set.

Bradbury et al. discloses a method of rapid design and manufacturing of biomedical devices with the concept of having implantable biomedical devices manufactured using a patient's own diagnostic imaged data. Further transmittal of the data is made over telecommunication or over globally based information network to facilitates the design of an implant customized for a particular patient as illustrated in [box 13]. Bradbury et al. further discloses a central website that could be used for maintaining records of inventory of predict usage patterns and inventory of raw materials. Bradbury et al. further discloses the concept of delivering manufacturing customized medical devices.

From this teaching of Bradbury et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the implanted medical device management system and method Duffin et al. to include the concept of a customized build-to-order and inventory information taught by Bradbury et al. in order to fit customer's specific needs.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffin et al. (5,752,976), in view of Bradbury et al. (2002/0007294 A1).

Duffin et al. discloses a medical device management system as claimed having a web-enabled information network (via 50), a programmer (via 20), at least one implanted medical device having specific features (12, 14), deployed from a known source (physicians office or clinic). The web-enabled information network (50) is in bi-directional data communications scheme with the programmer (20) (col. 5, lines 31-37). The web-enabled information network (50) includes one of a satellite based telecommunications link and a cellular link (col. 6 lines 27-35). The at least one implanted medical device (12, 14) includes data relating to specific device functions and/or features for example a voice alert in the patient's own language (col. 10, lines 24-29), patient's name and identification number or name of the implanting institution

and physician (col. 14, lines 39-47). The known source includes at least one of a hospital with data communications with the web-enabled information network (col. 5, lines 38-50).

However, Duffin et al. fails to disclose the implanted medical device having specific features including customized featured having customized data set downloadable to the web-information network to thereby route device information to the manufacturing facility to start a build-to-order/build-to-replenish operation, and in data communication with shipping/delivery and maintain an inventory.

Bradbury et al. discloses a method of rapid design and manufacturing of biomedical devices with the concept of having implantable biomedical devices manufactured using a patient's own diagnostic imaged data. Further transmittal of the data is made over telecommunication or over globally based information network to facilitates the design of an implant customized for a particular patient as illustrated in [box 13]. Bradbury et al. further discloses a central website that could be used for maintaining records of inventory of predict usage patterns and inventory of raw materials. Bradbury et al. further discloses the concept of delivering manufacturing customized medical devices.

From this teaching of Bradbury et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the implanted medical device management system and method Duffin et al. to include the concept of a customized build-to-order and inventory information taught by Bradbury et al. in order to fit customer's specific needs.

Response to Arguments

7. Applicant's arguments with respect to claims 1-7 have been considered but are moot in view of the new ground(s) of rejection. The Examiner has withdrawn the rejection under 103(a) since the claimed invention were, at the time the invention was made, subject to an obligation of assignment to the same person.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Dr. David M. Anderson, "Spontaneous Build-To-Order" Copyright 2001, <http://www.design4manufacturability.com> discloses the concept of quickly build standard customized products upon receipt of spontaneous orders without inventory or purchasing delays.

James Carbone, "Most OEMs Build-To-Order" April 1999, Purchasing Magazine Online discloses a build to order model system in electronic original equipment manufacturers.

Vrhel et al. (6,543,047 B1) discloses a build-to-order manufacturing method for producing custom configured computer system.

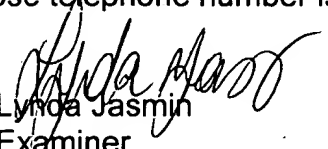
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda Jasmin whose telephone number is (703) 305-0465. The examiner can normally be reached on Monday- Friday (8:00-5:30) alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert P Olszewski can be reached on (703) 308-5183. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1113.



Linda Jasmin
Examiner
Art Unit 3627

lj
August 10, 2003